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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,684	04/27/2001	Toshifumi Mikayama	021286/027 6339	3283

27500 7590 03/08/2004

PILLSBURY WINTHROP LLP  
ATTENTION: DOCKETING DEPARTMENT  
11682 EL CAMINO REAL, SUITE 200  
SAN DIEGO, CA 92130

EXAMINER

GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/844,684	<b>Applicant(s)</b> MIKAYAMA ET AL.	
	<b>Examiner</b> Phillip Gambel	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3,6,8,24-26,30-61 and 65-78 is/are pending in the application.
- 4a) Of the above claim(s) 30-61 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 66 is/are allowed.
- 6) ☒ Claim(s) 3, 6, 8, 24-26, 65-78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's amendment, filed 12/11/03, has been entered.  
Claims 1-2, 4-5, 7, 9-22, 27-29 and 62-64 have been canceled.  
Claims 6, 8, 23-25, and 65 have been amended.  
Claims 67-78 have been added.

Claims 3, 6, 8, 24-26, 30-61, 65-78 are pending.

Claims 3, 6, 8, 24-26 and 65-78 are under consideration in the instant application as they read on the elected invention.

Claims 30-61 have been withdrawn from consideration by examiner under 37 CFR 1.142(b), as they read on the non-elected inventions.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.  
This Action will be in response to applicant's arguments, filed 12/11/03.  
The rejections of record can be found in the previous Office Action.
3. Applicant's provision of a new oath or declaration in compliance with 37 CFR 1.67(a) on 12/11/03 is acknowledged.
4. Claims 3, 6, 8, 24-26, 65, 67-78 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that number 11, 72, F1-102, F4-465, F2-103, F5-77, F5-157 antibodies and associated hybridomas, including those hybridomas recited in claims 3, 65, 67-78 are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC § 112, first paragraph, may be satisfied by a deposit of the pertinent hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

Applicant's amendment, filed 12/11/03, asserts that the amendment and the biological deposits do not create any presumption that the deposited materials is required to satisfy 35 USC. § 112, first paragraph and asserts that access to the deposit is as provided under 37 CFR 1.808(a) and (b).

In contrast to applicant's assertions and as pointed out in the previous Office Action, it is apparent that number 11, 72, F1-102, F4-465, F2-103, F5-77, F5-157 antibodies and associated hybridomas are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If they are not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the pertinent hybridomas which produce these antibodies. See 37 CFR 1.801-1.809.

In addition, it is not readily apparent that applicant has satisfied that conditions under the Budapest Treaty, where applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Again, applicant is required to be satisfied to make the appropriate deposits and statements to obviate the rejection under 35 USC. § 112, first paragraph, for the deposit of the claimed biological materials.

5. Applicant's amended claims, filed 12/11/03 have obviated the previous rejections of claims 25-26 under 35 U.S.C. § 112, first paragraph, scope of enablement and written description.

6. Claims 3, 6, 8, 23-26, 65 and 67 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Applicant's amended claims have obviated the previous rejection under 35 U.S.C. § 112, second paragraph, with respect to the recitation of "modulating".

B) Claims 3, 6, 8, 23-26, 65 and 67 are indefinite in the recitation of "antibody is denoted number 11 or 72" followed by a number of different deposited hybridomas. However, the relationship of the 11 or 72 antibody and the particular hybridoma is unclear and ambiguous. Also there is more than one hybridoma indicated for each antibody.

Applicant is invited to provide clear and unambiguous claims as they read on antibody 11 or antibody 12 and its appropriate hybridoma(s).

C) Claim 8 is indefinite in the recitation of "hybridoma of ... claim 3" because claim 3 is drawn to an antibody and not hybridoma. Therefore claim 8 lacks proper antecedent basis of claim 3 with respect to the "hybridoma of ... claim 3".

D) Claim 23 stands indefinite in that it depends on a compound claim, yet recites a composition claim. Therefore, the claims lack proper antecedent basis.

C) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

7. Applicant's amended claims, filed 12/11/03 have obviated the previous rejections under 35 U.S.C. § 102(e) as being anticipated by Kucherlapati et al. (U.S. Patent No. 6,150,584) and unpatentable under 35 U.S.C. § 103(a) as being unpatentable over Kucherlapati et al. (U.S. Patent No. 6,150,584) in view of de Boer (U.S. Patent No. 5,874,082).

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8. Claim 66 is allowed.

As indicated previously, due to high polymorphism of antibodies, the specific antibodies set forth in claim 3 and their respective hybridomas are deemed structurally distinct on the primary amino acid basis and therefore free from the prior art.

9. No claim is allowed.

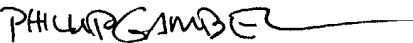
10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Phillip Gambel, PhD.  
Primary Examiner  
Technology Center 1600  
March 3, 2004